**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| **IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION**<br><br>**This Document Relates to the TPP Trial Subclasses** | MDL No. 2875<br><br>Honorable Robert B. Kugler, District Court Judge |

**TPP TRIAL DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS OF DR. LAUREN J. STIROH**

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**RULE**

Plaintiffs seek to exclude any opinions from Dr. Lauren J. Stiroh that relate to "how a [third-party payer ('TPP')] would have acted in the '[b]ut-[f]or' [w]orld" or the need of TPPs to pay for "alternative products" if the at-issue valsartan-containing drugs ("VCDs") had not been available. (Pls.' Mot. at 7.)[1] Plaintiffs offer essentially no legal authority in support of their motion, and their arguments frequently boil down to little more than the bare assertion that defense experts should be precluded from disagreeing with Plaintiffs' theory of the case. The Court should deny Plaintiffs' motion, just as it did when they sought to limit Dr. Stiroh's testimony at the class-certification stage of this litigation. (*See* ECF 2261, 85.)

***First***, Plaintiffs' unsupported assertion that an expert is prohibited from considering a counterfactual "but-for" world borders on the absurd. Economic damages experts routinely do just that in a wide variety of cases. And Plaintiffs' alternative argument that the only but-for world that may be considered is one in which VCDs were sold without impurities (as opposed to not sold at all) is similarly unavailing. After all, Dr. Stiroh's opinion responds to Plaintiffs' expert Dr. Conti,

[1] Plaintiffs' motion is entitled a motion to "exclude" rather than "partially exclude" Dr. Stiroh's testimony. But Dr. Stiroh offers numerous opinions that Plaintiffs do not seek to exclude, including her critique of Dr. Rena Conti's zero-value theory, her assertion that VCDs had therapeutic value to patients, and her explanation that TPPs fulfilled their obligations by purchasing the at-issue VCDs regardless of any impurities.

who opines that there was "no legitimate supply" of the at-issue VCDs and calculates damages premised on the assumption that the at-issue VCDs could not be sold.

***Second***, Plaintiffs also seek to exclude reference to the alternative medications that TPP class members would have had to purchase if the at-issue VCDs had been unavailable, but offer no support for this request. And Plaintiffs' complaint that Dr. Stiroh fails to quantify the cost of alternative drugs misunderstands her role as a defense rebuttal expert, which is to critique Dr. Conti, not to offer an independent damages calculation.

## BACKGROUND

Dr. Stiroh has a Ph.D. in economics from Harvard University and serves as a Senior Managing Director at NERA Economic Consulting. (Expert Report of Lauren J. Stiroh, Ph.D. ("Stiroh Rep.") ¶¶ 1, 4, June 28, 2023 (Pls.' Mot. Ex. 1).) She has "extensive experience" quantifying "economic damages" in "a range of industries[] including pharmaceuticals." (*Id.* ¶ 2.) As the Court acknowledged at the class-certification stage, she is well-qualified. (ECF 2261, 85.)

Based on her education and experience, Dr. Stiroh was asked to "evaluate and comment on the opinions and calculations presented in the declaration of Dr. Rena Conti . . . as they pertain to the existence and estimation of economic loss damages." (Stiroh Rep. ¶ 5.) Dr. Stiroh offers two overarching critiques of Dr. Conti's

conclusions.[2] First, Dr. Stiroh opines that Dr. Conti's "measure of economic loss is . . . inaccurate and meaningless" because it relies entirely on the theory "that all of the at-issue VCDs were uniformly worthless" and this zero-value theory is contrary to well-accepted economic principles. (*Id.* ¶ 8(i).) Second, she explains that Dr. Conti failed to consider "value received by TPPs." (*Id.* ¶ 8(ii).) In particular, Dr. Conti ignored that the purchase of the at-issue VCDs "fulfilled the same financial role that they would have regardless of alleged impurities," and that in a but-for world without the at-issue VCDs, class members would have had to purchase "an alternative hypertension treatment [that] would likely [have] cost TPPs at least as much." (*Id.*)

## ARGUMENT

Federal Rule of Evidence 702 requires that an expert's opinion (1) "help the trier of fact"; (2) "be based on sufficient factors or data"; and (3) "reflect[] a reliable application" of "reliable principles and methods." Fed. R. Evid. 702. Plaintiffs' motion primarily challenges Dr. Stiroh's opinion under the first prong of Rule 702, helpfulness to the trier of fact, a requirement usually "described . . . as . . . 'fit.'"

[2] Dr. Stiroh's two critiques center on errors in Dr. Conti's economic theory and misapplication of economic principles. Defendants' complex pharmaceutical claims and payments specialist, Wayne Gibson, separately critiques Dr. Conti's calculations on grounds centered in his field of expertise, including her erroneous reliance on overstated pricing data from the IQVIA Xponent data set and her inclusion of amounts the TPP class members never incurred, such as CMS subsidies and direct and indirect remuneration, in her calculation of Plaintiffs' total amounts paid.

*Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993). The standard for fit is "higher than bare relevance," but "not that high." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994). Dr. Stiroh's opinions easily fit the facts of the case and are admissible under Rule 702.

## I. DR. STIROH PROPERLY CONSTRUCTED A BUT-FOR WORLD.

Without citing any legal authority, Plaintiffs insist that it is categorically impermissible to present evidence at trial regarding an alternative world where Defendants did not manufacture or sell the at-issue VCDs. Initially, Plaintiffs claim that "'but-for' world modeling" and consideration of "'market' factors" are only relevant in antitrust cases. (Pls.' Mot. at 3.) It is hard to fathom why that would be, and Plaintiffs certainly do not explain it. Dr. Stiroh's task was to evaluate a model of "economic loss damages" allegedly suffered by TPPs (Stiroh Rep. ¶ 5); whether they suffered those "economic loss damages" because of violations of the antitrust laws or nitrosamine impurities is irrelevant to the damages model. Moreover, similar models are routinely used in non-antitrust cases. *See, e.g.*, *In re Takata Airbag Prod. Liab. Litig.*, MDL No. 2599, 2022 WL 3584510, at *1-2 (S.D. Fla. Aug. 12, 2022) (denying motion to exclude opinion on price-premium compared to "but-for world" in airbag defect case); *Peters v. Aetna Inc.*, No. 1:15-cv-00109-MR, 2019 WL 1429607, at *6 (W.D.N.C. Mar. 29, 2019) (explaining in non-antitrust case that

"[t]he initial step in a proper economic analysis of injury and damages is to define the 'but-for world'").

To the extent such opinions are challenged at all, it is generally for including too few market considerations in a but-for world, not for considering a but-for market in the first place. *See, e.g.*, *In re Gen. Motors LLC Ignition Switch Litig.*, 407 F. Supp. 3d 212, 234-39 (S.D.N.Y. 2019) (excluding opinion for failure to consider supply-side market factors in but-for world). Even *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, on which the Court relied to justify the admission of Dr. Conti's testimony at the class-certification stage, held that whether to consider market factors presented "a credibility dispute between the parties' experts," not that consideration of such factors was somehow inherently unreliable. 417 F. Supp. 3d 531, 557 (E.D. Pa. 2019) (cited in ECF 2261, 88-89).

Plaintiffs next contend that "if Dr. Stiroh were appropriately modeling the 'but-for' world in this litigation, she would have modeled . . . a situation where the Defendants . . . manufactured drugs that did not contain NDMA or NDEA" as opposed to one where the at-issue VCDs were simply not on the market at all. (Pls.' Mot. at 4.) Once again, Plaintiffs offer no explanation of why that is even the better but-for model, much less why it should be the only admissible model. Clearly, either option (selling medication without impurities or not selling the drugs at all) would comply with the law—Defendants were not under any affirmative obligation to sell

anything. Even more importantly, Dr. Stiroh's choice of a but-for world simply follows the lead of Plaintiffs' own expert Dr. Conti, whose zero-value opinion is predicated on the supposition that the at-issue VCDs "should not be available for sale in the United States." (Expert Decl. of Rena Conti, Ph.D. ¶ 44, Nov. 10, 2021 (ECF 2633-5 at Ex. 2).) Dr. Conti intends to testify that there was "no legitimate supply" of VCDs and that she can therefore erase any supply curve from an analysis of supply and demand. (*Id.* & fig. 2.) Dr. Stiroh's task was to "evaluate and comment on" Dr. Conti's opinions (Stiroh Rep. ¶ 5), an entirely appropriate task for a defense expert, *see, e.g.*, *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2021 WL 2352016, at *14 (E.D. Pa. June 9, 2021) (explaining role of rebuttal expert). As such, she necessarily had to adopt the same but-for world that Dr. Conti did—one where the at-issue VCDs were not sold.

## II. DR. STIROH PROPERLY CONSIDERED THE COST OF ALTERNATIVE TREATMENTS.

Plaintiffs' second argument stems from their first: they claim that acknowledging the alternative medications that class members would have had to pay for in the absence of at-issue VCDs renders Dr. Stiroh's opinion inadmissible. This is little more than a veiled attempt to argue that Plaintiffs' theory of the case is correct as a matter of law, and Defendants should be prohibited from challenging one of its major premises in front of a jury. The Court should reject it.

Once again, Plaintiffs' argument is not supported by a single citation to legal authority, and once again, the authority that does exist is to the contrary. Experts (even plaintiffs' experts) often testify to damages calculations that consider the cost of alternative medications. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, No. 04-cv-10739-PBS, 2011 WL 3852254, at *33-34 (D. Mass. Aug. 31, 2011) ("[B]ecause . . . physicians would have almost certainly prescribed alternative medication to their patients had they not prescribed Neurontin, [plaintiffs' expert] also calculated [TPP] plaintiffs' damages as the differences between the cost of Neurontin and the cost of the . . . more optimal drug that would have been prescribed."), *aff'd*, 712 F.3d 21 (1st Cir. 2013); *see also In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No 1871, 2013 WL 5761202, at *5 n.25 (E.D. Pa. Oct. 23, 2013) (acknowledging that TPPs might "have saved money" because some drugs "are priced similarly to Avandia" or are more expensive, though determining issue was "relevant to summary judgment," not the pleading stage).

Again, the only real question is whether an expert who ***fails*** to account for the cost of alternative medications is sufficiently reliable to testify, not whether accounting for such medications is allowed. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 159 (E.D.N.Y. 2008) (opinion admissible, but "[t]he jury can accept" the critique that "had the prescription not been written, the physician would likely have written a prescription for another medication, possibly even more expensive"),

*rev'd on other grounds sub nom. UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010).

Without any legal support for their position, Plaintiffs fall back on a *reductio ad absurdum* argument: "[t]aking Dr. Stiroh's opinion regarding 'alternative products' to its logical end, there would be no viable consumer goods litigation[] . . . , because a defendant would be able to claim that the Plaintiffs would have purchased something else." (Pls.' Mot. at 6.) For one thing, this argument ignores the difference between TPPs and direct consumers such as pharmaceutical patients. If a medication does not work, has undisclosed side effects, or contains genuinely dangerous impurities, a patient might be harmed regardless of cost. But a TPP cannot be at risk for cancer (nor, for example, could it have uncontrolled hypertension). The only harm it can suffer is monetary. As a result, it is clearly helpful for a jury to hear evidence about whether, and to what extent, the sale of the VCDs at issue actually left a TPP monetarily worse off. In any event, consideration of alternative medications does not foreclose TPP claims if the TPP has actually suffered any loss. In *Neurontin*, for example, the district court judge (in a bench trial) considered the cost of alternative mediations but still awarded tens of millions of dollars in damages based on "the difference between the cost of Neurontin and the cost of the cheaper and more optimal drug that would have been prescribed" in the absence of the defendants' misrepresentations. 2011 WL 3852254, at *59.

Finally, Plaintiffs argue that even if an expert could consider alternative medications, Dr. Stiroh has not "calculat[ed] the cost of" such alternatives here. (Pls.' Mot. at 5-6.) That critique misunderstands the role of a defense rebuttal expert. As explained above, Dr. Stiroh was retained by Defendants to critique the damages calculations offered by Plaintiffs' expert Dr. Conti. She did so, in part, by explaining the factors Dr. Conti failed to account for. Since Defendants do not bear the burden of proof, defense rebuttal experts have no obligation to offer any affirmative damages opinions of their own. *See, e.g.*, *Winn-Dixie*, 2021 WL 2352016, at *14 ("rebuttal expert witnesses may criticize other experts' theories and calculations without offering alternatives" and need not "produce models or methods of their own") (citations omitted); *Capri Sun GmbH v. Am. Beverage Corp.*, 595 F. Supp. 3d 83, 138 (S.D.N.Y. 2022) (defense experts have "a less demanding task because they have no burden to produce models or methods of their own; they need only attack those of plaintiff[s'] expert") (citation omitted).

For all of these reasons, Dr. Stiroh's discussion of the price of alternative medications is relevant and admissible.

## CONCLUSION

For the foregoing reasons, Plaintiffs' motion to exclude or limit the testimony of Dr. Lauren J. Stiroh should be denied.

Dated: February 26, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on February 26, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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